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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/787,231

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Karl F. Popp

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NATH & ASSOCIATES
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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/787,231	Applicant(s) POPP, KARL F.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-27,51-56 and 61-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,5-27, 51-56 and 61-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of IDS dated 9-30-04 and 5-25-04 is acknowledged.

Claims 2-4, 28-50 and 56-60 have been canceled. Claims 1, 5-27, 51-55 and 61-63 are pending.

Amended claims are now limited a method of treating **impetigo** of skin comprising topically administering to the skin of a patient a composition comprising a storage-stable mixture of benzoyl peroxide and clindamycin. Claims 26 recites that the composition of the claims is capable of treating various disorders. Independent claim 61 recites a method of treating impetigo in a patient having sensitive skin, with the same composition as in claim 1, wherein the composition is administered concomitantly or sequentially. All of the claims employ the same composition as in claim 1. Claim 61 requires the composition of claim 1 and an additional active agent.

Response to Arguments

1. Applicant's arguments with respect to claims 1, 5-27, 51-55 and 61-63 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

1. Claims 1, 5-27, 51-55 and 61-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. Instant claims, as described above, are directed to treating impetigo by topically administering to the skin of a patient in need thereof a topical composition in an amount effective to treat said bacterial disorder impetigo, wherein said topical composition comprises benzoyl peroxide and clindamycin. While the specification generally describes that the composition comprising the two active agents are useful for treating several bacterial disorders, applicants have not shown that they are in possession of a method of treating impetigo with the claimed active agents. Example 7 of the instant specification states that a patient suffering from impetigo is treated with a topical composition comprising benzoyl peroxide dispersion and a clindamycin as herein described and that it would be expected that the patient would improve his/her condition or recover. However, the example does not refer to which composition comprising the two components and further does not address as to what are the amounts of the active components, if each of them is present in an effective amount and if so what is an effective amount for the treatment of impetigo etc.

2. “[T]he essential goal’ of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed.” *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). With respect to this requirement, applicants have not shown that if they have invented a method of treating impetigo with the claimed composition because other than mere statement that the composition is used for treating impetigo, there is no evidence to show as to which type of patient- adult, children, human, non-human, is it for sensitive

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skin (as in claim 61 or irrespective of skin type as in claim 1), what are the amounts of the active agents or what constitutes an "effective amount", is it one drug or both drugs, Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). Further, the written description requirement promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. However, a showing of possession alone does not cure the lack of a written description. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 969-70, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). In this regard, the specification as described does not convey to one of an ordinary skill in the art that applicants are in possession of a method of treating impetigo with the composition of claim 1 because in example 7, applicants merely state what is expected from the treatment but what actually happened or if there was any therapeutic effect with such treatment. Further, as mentioned above claim 23 requires that the composition is capable of treating several other conditions claimed and in this regard, there is no descriptive support or evidence that

the composition of example 7 possess the capability of claim 23. Thus instant claims lack written descriptive support.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 5-27, 51-55 and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,117,843 Baroody et al in view of US 4,075,353 to Mandy et al

5. Baroody discloses a composition comprising clindamycin, benzoyl peroxide and a carrier, which is stable for several months (col. 2, L 3-66). Baroody discloses incorporating clindamycin salt that is compatible with the gelling agent and a dispersion of finely divided benzoyl peroxide, wherein the dispersion and clindamycin is combined with a carrier, and further with a gelling agent such as Carbopol (col. 4, L 1-43). Table 1 of Baroody shows final composition, which contains the claimed amounts of benzoyl peroxide and clindamycin, and has a pH of 4.5-5.5, which includes the pH of the instant claims. Baroody discloses applying the composition once or twice daily (col. 7, L 25-35). For claimed stability, Baroody shows that the composition is stable over a long period of time (table 7 and 8). The examples of Baroody show that the composition is highly effective against acne (col. 15-16) and therefore the composition of Baroody is effective against all the age groups (including those claimed). With respect to the viscosity, Baroody discloses that initial viscosity of benzoyl peroxide in the range of 50,000 to 90,000 and a final viscosity in the range of 70,000 to 120,000. Table 1 teaches humectant in the composition, which meets the requirement of additional component of

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claims 61-63. Baroody does not teach the purity of benzoyl peroxide, viscosity of benzoyl peroxide of claim 13, the percentage degradation of clindamycin or the amounts of benzoyl peroxide and clindamycin in the claimed standard deviation.

However, Baroody recognizes the factors i.e., pH, viscosity etc., that affect the stability (result- affective variables) of the composition and therefore it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ pure active compounds and optimize the general conditions such as viscosity, amounts of active agents with an expectation to achieve a composition that stable for long periods of time because the teachings of Baroody are also directed to preparing a storage stable composition comprising benzoyl peroxide and clindamycin.

Baroody teaches the composition for the treatment of acne but fails to teach the composition for the treatment of impetigo, claimed in the instant application.

Mandy teaches compositions comprising benzoyl peroxide for treating bacterial, parasitic infections including impetigo (col. Introduction and example 5). While Mandy teaches the treatment in animals such as dogs, instant claims do not specify what patient population is being treated. Mandy also teaches topical application of benzoyl peroxide. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made that the composition of Baroody would be effective for the treatment of impetigo because Mandy shows that topical treatment of animals with benzoyl peroxide composition effectively treats impetigo. In this regard, the claims of the instant invention does not specify if the one or both of benzoyl peroxide are effective in treating impetigo, nor did they show that clindamycin alone is effective in

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treating impetigo. According to the instant claims (as presented) benzoyl peroxide alone is sufficient to treat impetigo, and this is taught by Mandy. Thus, a skilled artisan would have expected that the composition of Baroody in the treatment of impetigo.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611

April 13, 2008